IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1797
VISTA HEALTHPLAN, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1833
APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-2768

Goldberg, J. **June 23, 2014**

MEMORANDUM OPINION

Before me are three motions for summary judgment filed in the consolidated antitrust lawsuit known as the In re Modafinil Litigation. The private Plaintiffs in these lawsuits are a putative class of direct purchasers (the King Drug case); a putative class of end payors (the Vista Healthplan case); a generic drug company (Apotex, Inc.); and several individual direct

purchasers that are not part of the putative class. The Federal Trade Commission is also a Plaintiff, but none of the motions addressed in this opinion implicate its case.

The Defendants are Cephalon, Inc., a brand-name manufacturer of pharmaceuticals, and four generic manufacturers: Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals, USA, Inc. (collectively "Teva"); Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy"); Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively "Mylan"), and Barr Laboratories, Inc. At the center of this case are four Hatch-Waxman reverse payment settlement agreements executed in 2005 and 2006 between Cephalon and each of the generic manufacturers. Those agreements resolved then-pending patent infringement lawsuits filed by Cephalon against the four generics (collectively, the Generic Defendants).

This opinion addresses whether these agreements were the product of an overall antitrust conspiracy between all of the Defendants. Based on the record before me, I conclude as a matter of law that such a conspiracy cannot be established. Accordingly, I will grant the motions for summary judgment filed by Cephalon and the Generic Defendants, and deny the motion for summary judgment filed by the Direct Purchaser Class Plaintiffs.

I. Factual and Procedural Background

The facts giving rise to this litigation commenced on October 6, 1994, when Cephalon filed a U.S. patent application titled "Acetamide Derivative Having Defined Particle Size." (Ford. Decl. Ex. D, '845 patent.) On April 8, 1997, the Patent and Trademark Office issued the patent as U.S. Patent No. 5,618,845. (Id.) Cephalon later applied for a reissue of this patent, which resulted in the issuance of U.S. Patent RE37,516 (the '516 patent). (Ford Decl. Ex. E, '516 patent.)

Following the issuance of the '845 patent, the Food and Drug Administration (FDA) approved Cephalon's New Drug Application (NDA) for Provigil, which Cephalon began marketing in February 1999. (Ceph SOF ¶ 4.) The active ingredient in Provigil is modafinil, "a wakefulness-promoting agent" used to treat narcolepsy and other sleep disorders. (Ford Decl. Ex. A, NDA 20-717.) Provigil quickly became Cephalon's most successful product, with U.S. sales of approximately $475 million in 2005, accounting for 40% of Cephalon's worldwide revenue. (Ceph. SOF ¶ 5.) The FDA listed Provigil in the "Orange Book" as an approved drug, and Cephalon submitted the '845 patent (later substituted by the '516 patent) as covering Provigil. (DPCP SOF ¶7.)

At the same time it received FDA approval, Cephalon received "New Chemical Entity" exclusivity, entitling it to five-years of competition-free sales, a period that was set to expire on December 24, 2003. (DPCP SOF ¶ 3.); see also 21 U.S.C. § 355(c)(3)(E)(ii). Cephalon also received a seven year period of exclusivity based on Provigil's designation as an "Orphan Drug,"[1] which extended the marketing exclusivity period to December 24, 2005. (DCPC SOF ¶ 4.) On March 22, 2006, Cephalon obtained "Pediatric" exclusivity, which added six months to the exclusivity periods, set to end with the expiration of the '516 patent on October 6, 2014. (Ceph. SOF ¶ 10; DPCP SOF ¶ 5.); see also 21 U.S.C. § 355a(c). Thus, the '516 patent term would potentially be extended to April 6, 2015.

[1] An orphan drug is one used to treat a rare disease or ailment. Because the drug will be purchased by only a small number of persons, pharmaceutical companies may lack the financial incentive to develop drugs for such diseases. To combat this problem, Congress passed the Orphan Drug Act, which provides various benefits to the sponsor of an orphan drug. Perhaps most importantly, the Act provides for a seven-year period of non-patent related marketing exclusivity. See Baker Norton Pharma., Inc. v. U.S. Food & Drug Admin., 132 F. Supp. 2d 30, 31-32 (D.D.C. 2001).

Under federal law however, other drug companies did not have to wait until 2015 to seek approval to market a generic version of Provigil. The Hatch-Waxman Act, designed to encourage the development and marketing of generic versions of approved drugs, permits a generic drug manufacturer to receive approval after filing an "Abbreviated New Drug Application," otherwise known as an ANDA. An ANDA filer can piggyback on the NDA filer's safety and efficacy studies, which the FDA has already reviewed in approving the listed drug. To obtain approval, the ANDA filer must show that its generic drug and the relevant listed drug contain the same active ingredients and are otherwise "bioequivalent." See generally Caraco Pharma. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1281-86 (Fed. Cir. 2008). In addition, where the branded drug is covered by a patent listed in the Orange Book, the ANDA filer must make one of the following four certifications: (I) that required patent information has not been filed with the FDA; (II) that the relevant patent is expired; (III) that the patent will expire on a particular date and the FDA should defer approval of the ANDA until the patent expires; or (IV) that the patent is invalid or will not be infringed by the generic drug. See Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1356 (Fed. Cir. 2008).

In the case of Provigil, the earliest date on which generic companies could submit an ANDA with a paragraph IV certification was December 24, 2002. (DPCP SOF ¶ 8.) The four Generic Defendants filed ANDAs with a paragraph IV certification on that date. (DPCP SOF ¶ 9.) This same-day filing was significant because, under Hatch-Waxman, as an incentive for generic companies to challenge weak patents, the first applicant to file an ANDA with a paragraph IV certification is entitled to a 180-day period of exclusivity for its generic drug, beginning on the day it first markets its drug commercially. F.T.C. v. Actavis, 133 S. Ct. 2223, 2228-29 (2013). This exclusivity period can be "worth several hundred million dollars." Id. at

2229 (quoting Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). Because all four generics filed on the same day, they were entitled to share the exclusivity period. (DPCP SOF ¶ 10.)

Filing a paragraph IV certification "automatically counts as patent infringement," and thus often prompts the patent-holder to file a lawsuit. Actavis, 133 S. Ct. at 2228. Under another feature of the Hatch-Waxman regime, when the patent-holder files an infringement lawsuit within 45 days of the ANDA filing, the FDA is barred from approving the generic company's ANDA for a period of 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). If the case is resolved during the 30-month stay, the FDA will take action on the ANDA consistent with the court's judgment. Actavis, 133 S. Ct. at 2228. If the case is still ongoing during that period, the FDA may approve the ANDA, at which point the generic company will have to decide whether to sell its drug "at risk" of incurring damages should the infringement case result in a judgment in favor of the patent holder. Id.

On March 28, 2003, Cephalon chose to sue all four Generic Defendants for infringement in the District of New Jersey, triggering the 30-month stay. (DPCP SOF ¶ 13-14.) Each of the Generic Defendants filed Answers alleging that their respective generic drugs would not infringe the '516 patent, and asserting that the '516 patent was invalid. (EPCP SOF ¶ 5.) Three of these Answers (Teva, Ranbaxy, and Mylan) were amended to add allegations of inequitable conduct in the procurement of the '516 patent. (EPCP SOF ¶ 6.) During the course of this litigation, the Generic Defendants shared a number of expert witnesses. (EPCP SOF ¶ 9.) At the summary judgment stage, each of the four Generic Defendants filed a motion for summary judgment: Teva sought summary judgment on non-infringement, Ranbaxy sought summary judgment on

invalidity and non-infringement, Mylan sought summary judgment on invalidity, and Barr sought summary judgment on non-infringement. (DPCP SOF ¶ 16.)

These motions were never decided, because between October 2005 and February 2006, Cephalon entered into settlement agreements whereby each Generic Defendant was paid a substantial amount of money.[2] (DPCP SOF ¶ 18.) There is no dispute that each negotiation took place separately, nor is there any dispute that Cephalon proposed the same central term to each Generic: if the Generic would agree not to make, use, or sell a generic version of Provigil until April 6, 2012, Cephalon would grant the Generic a non-exclusive license to make and sell generic Provigil, effective on that date. (DPCP SOF ¶¶ 16, 19.) The April 2012 licensing date was thus three years before the date Cephalon's patent was set to expire.

In addition to the April 6, 2012 generic entry date, each settlement agreement contained a "contingent launch" provision, which permitted each settling Generic to sell its product prior to April 6, 2012 if any other company brought a generic version of Provigil to market. (Ceph. SOF ¶ 23.) Following the execution of each settlement agreement, Cephalon announced these two core terms (the April 2012 date certain and the contingent launch provision) via press releases.[3]

[2] The settlement agreements were executed on the following dates: the Teva agreement was executed on December 8, 2005, effective December 4, 2005; the Ranbaxy agreement was executed on December 22, 2005, effective the same day; the Mylan agreement was executed on January 9, 2006; and the Barr agreement was executed on February 1, 2006. (Ceph. SOF ¶¶ 24, 30, 37, 43.)

[3] (Hennings Decl. Ex. 22 (12/9/05 Press Release Announcing Cephalon-Teva Settlement); Id. Ex. 26 (12/22/05 Press Release Announcing Cephalon-Ranbaxy Settlement); Id. at Ex. 28 (1/10/06 Press Release Announcing Cephalon-Mylan Settlement); Id. at Ex. 30 (2/1/06 Press Release Announcing Cephalon-Barr Settlement).)

After the patent infringement actions were dismissed, the antitrust lawsuits were filed before this court in mid-2006.[4]

II. The Parties' Positions Regarding An Overall Antitrust Conspiracy

The private Plaintiffs' complaints all allege a conspiracy between all of the Defendants to restrain trade and monopolize the market for modafinil. I previously ruled that this allegation, along with the other evidence alleged in the Complaint, was sufficient to withstand a motion to dismiss. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514, 532-33 (E.D. Pa. 2010). Now that discovery has been completed, I must decide whether the evidence of record would permit a jury to consider these claims.

The Direct Purchaser Class Plaintiffs have moved for summary judgment, asserting that the undisputed evidence establishes that Cephalon helped to broker an illegal "inter-generic" conspiracy to keep generic Provigil off the market until April 2012. In their view, the substantially identical contingent launch provisions ensured that no Generic Defendant would lose out on the 180-day exclusivity period should another Generic Defendant launch earlier than the agreed April 6, 2012 date certain. It is alleged that this assurance served to dull the incentive each Generic Defendant would otherwise have had to launch its product as early as possible. The Direct Purchasers point to Cephalon's company newsletter, in which it described the contingent launch provisions as "provid[ing] the comfort level each generic litigant needed to settle, serving to assure them that no opportunity would be lost should another firm launch at risk." (Hennings Decl. Ex. 12 (Brainwaves Article).) The Direct Purchasers urge that this type of agreement, coordinated by Cephalon, was essentially a conspiracy among the Generic Defendants to avoid

[4] The FTC's case was filed in 2008 in the District of Columbia, and was subsequently transferred to this district. Federal Trade Comm'n v. Cephalon, 551 F. Supp. 2d 21 (D.D.C. 2008).

competition with one another and cede the modafinil market to Cephalon in exchange for large settlement payments. They assert that this agreement, as a form of market division among horizontal competitors, is per se illegal under the Sherman Act. See Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitve that each is illegal per se without inquiry into the harm it has actually caused.").

Defendants acknowledge that the contingent launch provision was important to each Generic's decision to settle, but point out that each Generic had an independent incentive to demand such a provision. Specifically, each Generic qualified for the 180-day exclusivity period, and it was only natural to attempt to protect their entitlement to that exclusivity by negotiating a provision that permitted them to enter the market whenever that period started (i.e., upon the entry of any of the other Generic Defendants).

Defendants rely in part on numerous cases that stand for the proposition that in order to prove a conspiracy, an antitrust plaintiff must present evidence that tends to exclude the possibility that the defendants acted independently. Because the Plaintiffs have not presented evidence tending to exclude the possibility that each Generic Defendant acted independently, Defendants urge that summary judgment in their favor is appropriate on the inter-generic conspiracy claim. Defendants also stress that "conscious parallelism," that is, similar conduct undertaken without agreement or coordination, does not violate the antitrust laws.

While the above motions are essentially cross-motions for summary judgment on the overall conspiracy issue, other, non-moving Plaintiffs urge in their opposition that, even if the Direct Purchasers are not entitled to summary judgment, the evidence of record is sufficient to permit a jury to find an overall conspiracy.

III. Burden at the Summary Judgment Stage

Under the Sherman Act, "[e]very . . . conspiracy, in restraint of trade or commerce among the several States, . . . is declared to be illegal." 15 U.S.C. § 1. Thus, the "existence of an agreement is the hallmark of a Section 1 claim." In re Baby Food Antitrust Litig., 166 F.3d 112, 117 (3d Cir. 1999). This agreement may be proven by either direct or circumstantial evidence. Direct evidence "is explicit and requires no inferences to establish the proposition or conclusion being asserted." InterVest, Inc. v. Bloomberg, L.P., 340 F.3d 144, 159 (3d Cir. 2003) (quoting Baby Food, 166 F.3d at 118). Because direct evidence of an unlawful conspiracy—a "smoking gun"—is often unavailable, proof by inferences drawn from circumstantial evidence is the norm. Id.

The problem with circumstantial evidence, however, is the risk that a fact-finder may draw the incorrect inferences, and therefore mistake legitimate competitive activity for unlawful collusion. In the antitrust context, these mistakes are especially harmful, because they risk punishing—and thus discouraging—the pro-competitive conduct that the antitrust laws are designed to promote and protect. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986) ("[M]istaken inferences in cases such as this one are especially costly, because they chill the very conduct the antitrust laws were designed to protect."). In recognition of this delicate balancing, the Supreme Court has concluded that "antitrust law limits the range of permissible inferences [that may be drawn] from ambiguous evidence in a § 1 case." Id. at 588. Thus, where conduct potentially explainable by an illegal conspiracy is equally consistent with permissible competition, an inference of conspiracy cannot be drawn. Id. Instead, to survive summary judgment, "[t]here must be evidence that tends to exclude the possibility that the

[alleged conspirators] were acting independently." Monsanto Co. v. Spray-Rite Serv. Corp., 465 U.S. 752, 764 (1984).

Circumstantial evidence of conspiracy often takes the form of "conscious parallelism," that is, similar conduct by the alleged conspirators, of which each of the conspirators are aware. For example, one seller might raise its prices, only to have other sellers in the market follow suit with a similar price increase. Although this would benefit the sellers and hurt consumers, the Supreme Court "ha[s] made it clear that neither parallel conduct nor conscious parallelism, taken alone, raise the necessary implication of conspiracy." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 561 n.7 (2007). Accordingly, the United States Court of Appeals for the Third Circuit has held that, to permit an inference of conspiracy from consciously parallel behavior, a plaintiff must also show "plus factors" that tend to distinguish legal parallel behavior from a conspiracy. InterVest, 340 F.3d at 165. Although the list of plus factors has never been stated in exhaustive terms, the Third Circuit has identified three: "(1) evidence that the defendant had a motive to enter into a . . . conspiracy; (2) evidence that the defendant acted contrary to its interests; and (3) 'evidence implying a traditional conspiracy.'" In re Insurance Brokerage Antitrust Litig., 618 F.3d 300, 322 (3d Cir. 2010) (internal quotation mark omitted) (quoting In re Flat Glass Antitrust Litig., 385 F.3d 350, 360 (3d Cir. 2004)).

Despite the more specific inquiry required at the summary judgment stage in an antitrust case, the familiar rules still apply. Under Rule 56(a), I am required to view the facts in the light most favorable to the non-movant in deciding whether summary judgment is appropriate. Matsushita, 475 U.S. at 587. The ultimate question is whether the record reveals genuinely disputed facts that, if resolved in favor of the non-moving party, would permit a jury to find in that party's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

IV. Discussion

In assessing whether the evidence dictates that summary judgment be granted for either the Direct Purchasers or the Defendants, it is important to keep in mind precisely which claims these motions address. The motions at issue do not concern the legality of the individual, bilateral settlement agreements between Cephalon and each Generic Defendant. What is at issue is Plaintiffs' claim that the separate settlement agreements were in fact the manifestation of a horizontal conspiracy between all Defendants—with Cephalon at the center—to restrain trade in the modafinil market. At the summary judgment stage, the question is thus whether there is sufficient evidence to allow a jury to consider whether all Defendants were parties to a single agreement. (Or, for the Direct Purchasers, whether the evidence compels a finding as a matter of law, that all Defendants were parties to a single agreement.)

A. Direct Evidence of Conspiracy

Plaintiffs proffer the following as direct evidence of an overall, anticompetitive conspiracy: (1) the settlement agreements themselves, which contain substantially similar language and structure; (2) press releases announcing each settlement, including that each release contained the April 6, 2012 market entry date certain and the contingent launch provision; and (3) statements by negotiators for the Generic Defendants indicating that they were aware of the contingent launch and date certain provisions in negotiating their own agreements, including a statement that the Ranbaxy agreement was "modeled on the terms of the Teva settlement."[5] (Refsin Decl., Ex. K, 136:12-13).

[5] The Individual Plaintiffs also point to a file note written by Vincent Fabiano, the lead negotiator for Ranbaxy, outlining the terms of Cephalon's offer and noting that Cephalon "will give us a deal otherwise similar to Teva, i.e.[] launch in 2011 or 2012 with early launch upon launch by any other generic." (Refsin Decl., Ex. M.)

Whether this evidence is properly considered 'direct' depends on whether the fact-finder would have to take an additional logical step in order to conclude that a conspiracy occurred. In other words, an additional step is indicative of circumstantial evidence. Direct evidence requires no extrapolation, as with "a document or conversation explicitly manifesting the existence of the agreement in question." Insurance Brokerage, 618 F.3d at 324 n.23.

The Third Circuit has cited examples of evidence found to be direct evidence of an antitrust conspiracy: "(1) a direct threat to the plaintiff from a competitor that if [the plaintiff] went into business, his competitors would do anything they could to stop him, including cutting prices or supplies; (2) advising distributors that a supplier would cut off access if the distributor failed to maintain a certain price level; (3) a memorandum produced by a defendant conspirator detailing the discussions from a meeting of a group of alleged conspirators; (4) a public resolution by a professional association recommending that its members withdraw their affiliation with an insurer." Cosmetic Gallery, Inc. v. Schoeneman Corp., 495 F.3d 46, 52 (3d Cir. 2007) (citations omitted).

In contrast, even evidence that competitors exchanged extensive pricing information may not be direct evidence of a price-fixing conspiracy, because it still requires inferences to be drawn about whether the exchange was related to an agreement to adopt particular pricing policies. Baby Food, 166 F.3d at 120-21; see also Monsanto, 465 U.S. at 762 (observing that "the fact that a manufacturer and its distributor are in constant communication about prices and marketing strategy does not alone show that the distributors are not making independent pricing decisions").

After examination of the direct evidence of record, I disagree with Plaintiffs that this evidence indisputably establishes a conspiracy such that summary judgment should be granted in

their favor. The settlement agreements themselves are individual agreements, not global agreements amongst all Defendants. Plaintiffs are unable to point to any direct evidence that the Generics agreed amongst themselves, let alone that such overall agreement also included Cephalon. Indeed, each agreement runs only between Cephalon and a single Generic. While Plaintiffs are correct that the settlements contain similar terms, and it could be argued that this similarity is evidence of an overall conspiracy, that is classic circumstantial, not direct evidence.

Similarly, the press releases, like the pricing information exchanged in Baby Food, are not unambiguous evidence of an agreement, because there are potentially innocent explanations for the statements contained in these releases. While the awareness of the press releases and the essential terms of the settlements might demonstrate the "conscious" element of conscious parallelism, it is not direct evidence of an anticompetitive conspiracy such that summary judgment is warranted. Because I conclude that there is insufficient direct evidence of an overall conspiracy, the analysis must proceed to examining the record regarding circumstantial evidence.

B. Circumstantial Evidence of Conspiracy

The Direct Purchasers urge that the circumstantial evidence of record indisputably demonstrates an agreement between Cephalon and the Generic Defendants to restrain trade in the modafinil market. I will examine each piece of circumstantial evidence cited by Plaintiffs in a light most favorable to their position.

First, Apotex points out that the legal effect of the settlement agreements, in conjunction with the Hatch-Waxman regime, was to create a "bottleneck," whereby no other generic was able to enter the market. This is because, at the times relevant to this case, the 180-day exclusivity period granted to an initial ANDA paragraph IV filer (in this case, the four Generic Defendants) operated by preventing the FDA from approving a subsequent paragraph IV filer's ANDA until

the end of the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv); see also Hemphill, supra, 81 N.Y.U. L. Rev. at 1586-88 (describing the "[a]pproval [b]ottleneck"). That exclusivity period began to run when one of the first-filers began to market its drug commercially, which the settlement agreements dictated would not be until at least April 6, 2012. Thus, if Apotex (or any other generic, for that matter) wanted to get on the market prior to October 6, 2012 (the end of the 180 days), it needed a judicial determination that Cephalon's patent was invalid or not infringed.

Ordinarily, Apotex might obtain this judicial determination by filing a declaratory judgment action, but that was not an option after the settlements with the Generic Defendants. Under the prevailing law at the time, Apotex could not file a declaratory judgment action seeking a judicial determination of invalidity or non-infringement unless it was in "reasonable apprehension" of an infringement lawsuit. See Teva Pharma. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1334 (Fed. Cir. 2005), abrogated by MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007). And because Apotex's ANDA could not be approved until the exclusivity period expired, Cephalon had no incentive to sue Apotex for infringement, meaning that the necessary "reasonable apprehension" did not exist. This is no longer the law, but as Apotex points out, the potential to create a bottleneck gave Cephalon a strong incentive to settle with all four Generic Defendants, rather than a subset. Plaintiffs assert that the opportunity to create a bottleneck assured that the anticompetitive effect of the settlements would not be undone by a subsequent challenger like Apotex, and thus provides circumstantial evidence of an overall conspiracy.

Second, Plaintiffs point to the substantial similarities between the four individual settlement agreements as evidence of an overall conspiracy. They observe, for example, that each agreement contained the same "date certain" of April 6, 2012 for entry into the generic modafinil

market.[6] Plaintiffs stress that each agreement ensured that all of the Generic Defendants would enter the market on the same date by providing for an accelerated entry date whenever another of the Generic Defendants reached the market with its modafinil drug.[7] Just as the contingent launch provisions linked the Generic Defendants together for the purpose of entry dates, Plaintiffs note that Ranbaxy and Mylan each negotiated provisions that would permit them to audit any other modafinil license agreements Cephalon had entered into (such as the Settlement Agreements with the other Generics), and elect to receive the most favorable royalty rates in any of those agreements. Thus, at least for Ranbaxy and Mylan, the negotiations concluded in contractual assurances that each firm would not only be allowed to enter the modafinil market at the same time any other Generic Defendant entered, but further that they would be entitled to receive the most favorable royalty rates obtained by any other Generic Defendant.[8]

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[6] (Hennings Decl. Ex. 21, Teva Settlement Agreement, at § 3.1.1; Hennings Decl. Ex. 24, Ranbaxy Settlement Agreement, at § 3.1.1; Hennings Decl. Ex. 27, Mylan Settlement Agreement, at § 3.1.1; Hennings Decl. Ex. 29, Barr Settlement Agreement, at § 3.2.)

[7] More specifically, the agreements explicitly addressed three situations in which another generic version of modafinil might reach the market before the date certain. First, Cephalon might negotiate an earlier entry date with another generic manufacturer. (Hennings Decl. Ex. 21, Teva Settlement Agreement, at § 3.1.2; Hennings Decl. Ex. 24, Ranbaxy Settlement Agreement, at § 3.1.2; Hennings Decl. Ex. 27, Mylan Settlement Agreement, at § 3.1.2; Hennings Decl. Ex. 29, Barr Settlement Agreement, at Ex. A § 2.2(b).) Second, a non-settling Generic Defendant might continue to litigate and launch "at-risk" at the end of the 30-month stay. (Hennings Decl. Ex. 21, Teva Settlement Agreement, at § 3.1.3; Hennings Decl. Ex. 24, Ranbaxy Settlement Agreement, at § 3.1.3; Hennings Decl. Ex. 27, Mylan Settlement Agreement, at § 3.1.3; Hennings Decl. Ex. 29, Barr Settlement Agreement, at Ex. A § 2.2(c).) Third, a non-settling Generic Defendant might continue to litigate and obtain a non-appealable final judgment that Cephalon's patent was either invalid or not infringed. (Hennings Decl. Ex. 21, Teva Settlement Agreement, at § 3.1.3.7; Hennings Decl. Ex. 24, Ranbaxy Settlement Agreement, at § 3.1.3.7; Hennings Decl. Ex. 27, Mylan Settlement Agreement, at § 3.1.3.7; Hennings Decl. Ex. 29, Barr Settlement Agreement, at Ex. A § 2.2(d).) Under each of these contingencies, the settling Generic Defendant would be allowed to enter the market.

[8] (Hennings Decl. Ex. 24, Ranbaxy Settlement Agreement, at § 3.5; Hennings Decl. Ex. 27, Mylan Settlement Agreement, at § 3.6.)

Third, as further circumstantial evidence of an overall conspiracy, Plaintiffs point to public disclosures of key settlement terms that followed the execution of each agreement. Specifically, each settlement was followed by the issuance of one or more press releases announcing three terms: (1) the April 2012 date certain for market entry; (2) the contingent launch provision; and (3) business arrangements, such as licenses to intellectual property or modafinil supply agreements. (Hennings Decl. Ex. 22-23, 25-26, 28-31.) Similar information was also disclosed in filings with the Securities and Exchange Commission. (E.g., GD Ex. 24.) Plaintiffs also stress that each Generic Defendant acknowledged being aware of the respective settlement agreements and the details disclosed in the press releases prior to or during negotiations with Cephalon, and always before its own settlement agreement was executed.[9]

Fourth, in negotiating the contingent launch provisions (as well as the royalty-matching provisions in the Ranbaxy and Mylan agreements), Plaintiffs point out that each Generic Defendant admitted that its motive was to preserve for itself the 180-day exclusivity period and to ensure that a launch by another Generic Defendant prior to the date certain would not "unduly harm" its interests. (DPCP SOF ¶ 36.) For example, Plaintiffs highlight the deposition testimony of Brian Seth Roman, Mylan's Senior Vice President, when he was asked whether anyone at Mylan told Cephalon "that you wanted the same entry conditions that Teva and Ranbaxy got":

> I know I never said it that way.
>
> . . . I know there was some discussion about us not wanting to be disadvantaged relative to the other companies . . . that had settled and for that

[9] For example, one of Ranbaxy's lead negotiators received a copy of the press release announcing the Cephalon-Teva settlement on December 9, 2005, almost two weeks prior to the execution of the Cephalon-Ranbaxy settlement. (Grogan Decl. Ex. N.) One of Mylan's lead negotiators testified that he was aware of both the Teva and Ranbaxy settlements prior to negotiating with Cephalon. (Grogan Decl. Ex. R, at 73:21 to 74:7.) Barr, the last Generic Defendant to settle, was similarly aware of the three prior agreements before executing its Settlement Agreement with Cephalon. (Grogan Decl. Ex. Z.)

> reason we wanted a provision in the agreement about the royalties that could give us some comfort that we weren't paying more in royalties than the other companies were.
>
> In terms of entry date, my recollection is that the public announcements of the earlier settlements said something about the entry date that had been agreed upon. It was my understanding that the entry date we were agreeing on, which is three years before the patent expired or earlier if another generic launched, was the same in terms of timing.
>
> Again, I don't think I put it to them that way, but there were two issues, both the royalty side and the entry timing, that we didn't want to be disadvantaged relative to the others.

(Hennings Decl. Ex. 36, Roman Dep., at 119:23 to 120:16.) The Direct Purchasers also point to similar statements from representatives of the other Generic Defendants, all indicating that in negotiating a settlement with Cephalon, one of their primary objectives was to ensure that they were not disadvantaged relative to the other settling generics.[10] (DPCP SOF ¶¶ 37-44.)

According to Plaintiffs, the evidence and legal framework discussed above paint a picture of an overall conspiracy that looks something like this: Cephalon, with its monopoly over modafinil products, stood to gain more in profits from its continued monopoly than the Generic Defendants could hope to earn by launching competing low-cost generic products. See Actavis, 133 S. Ct. at 2235 (noting that "there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market"). In light of this realization, the Generic Defendants, despite their recognition that Cephalon's patent was vulnerable, concluded that it was in their best interest to allocate all modafinil sales to Cephalon—allowing Cephalon to rack up

[10] As Apotex points out, for the purposes of summary judgment, I must assume that Cephalon obtained the '516 patent through fraud on the Patent Office, despite my decision not to give collateral estoppel effect to my prior ruling on that issue. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 982848 (E.D. Pa. March 13, 2014). I do not, however, consider that fact significant to my analysis of the overall conspiracy motions addressed here.

monopoly profits—in exchange for substantial payments from Cephalon. (DPCP 2nd Am. Compl. ¶ 180.) To ensure that there would be no "cheaters," all agreed to the contingent launch provision, which virtually eliminated the incentive any of the Generic Defendants would have had to try to reach the market earlier than the agreed-upon date certain. The Plaintiffs posit that, based on this circumstantial evidence, a jury could conclude that an overall conspiracy existed.

Where antitrust conspiracy claims are levied, it is not sufficient to show that the participants in the alleged conspiracy acted in parallel ways, especially where there are equally plausible independent explanations. Matsushita, 475 U.S. at 588. And here, as Defendants stress, the incentives provided under the agreements with the individual generic companies provide an obvious potentially independent explanation. Indeed, although Cephalon proposed the April 6, 2012 "date certain" for market entry, in return for accepting that date, each individual Generic Defendant was compensated separately. This alone could suggest that there is no link with the other Generics. Apotex points out that Cephalon overpaid all Generic Defendants to supply it with modafinil, and spent millions to license intellectual property. But this evidence could also be viewed as a separate lucrative licensing agreement having nothing to do with an overall conspiracy. (Br. of Apotex 15-17.) Ranbaxy and Mylan received further assurances that they would get favored treatment with respect to royalty rates. And the Direct Purchasers urge that the contingent launch provisions held significant value for each Generic Defendant, in that it gave them the "comfort" of knowing that they would not lose the opportunity to launch should another Generic Defendant negotiate or otherwise obtain an earlier entry date. (DPCP SOF ¶¶ 33-44.) While this evidence may be useful in showing that the individual agreements may be susceptible to antitrust scrutiny under the Actavis test, at the same time it undermines Plaintiffs' overall conspiracy theory by highlighting the independent reasons each Generic Defendant had for

accepting Cephalon's terms. Thus, what Plaintiffs cast as facts establishing an overall conspiracy could also be viewed as "independent responses to common stimuli." Insurance Brokerage, 618 F.3d at 325 (quoting Twombly, 550 U.S. at 556 n.4).

Under these circumstances, where parallel conduct with non-conspiratorial explanations is present, the "plus" factors set forth in Insurance Brokerage become important in determining whether the evidence would allow the jury to reasonably draw an inference of conspiracy. Of the factors identified in Insurance Brokerage, the parties focus primarily on whether the evidence reflects that Defendants acted contrary to their own economic self-interests.

Under this test, Plaintiffs assert that the settlement agreements were against Defendants' economic self-interest because "[a]bsent the conspiracy, it was in each Generic Defendant's independent self-interest to enter the market as early as possible without regard to the entry date of its fellow Generic Defendants." (Br. of Individual Pls. 15.) Cephalon responds that the similarity between the settlement agreements resulted from the "independent dynamics of each settlement negotiation," in that Cephalon stood firm on the April 6, 2012 date certain, while the contingent launch provisions resulted from each Generic Defendant's "plainly logical desire . . . to retain the Hatch-Waxman benefits of 'first-filer' status." (Br. of Ceph. 2.) Thus, Defendants stress that all of the Generic Defendants had independent reasons for accepting the settlements.

The economic self-interest inquiry seems to be especially useful in cases like this one, where the antitrust plaintiff attempts to infer a horizontal agreement among signatories to separate agreements with a common participant.[11] Willing acceptance of an agreement that

[11] Oftentimes, these cases arise in the context of individual vertical agreements, from which the plaintiff attempts to infer a horizontal or overall conspiracy. See Toys "R" Us v. Federal Trade Commission, 221 F.3d 928, 934-36 (7th Cir. 2000) (holding that substantial evidence supported finding of horizontal agreement where there was a series of vertical agreements between toy retailer and toy manufacturers); In re Elec. Books Antitrust Litig., 859 F. Supp. 2d 671, 682-83

"contravene[s] each defendant's self-interest 'in the absence of similar behavior by rivals,'" might well suggest that the defendant has received assurances that all its rivals will act similarly. Starr v. Sony BMG Music Entertainment, 592 F.3d 314, 327 (2d Cir. 2010) (emphasis added) (quoting 7 Areeda & Hovenkamp, Antitrust Law § 1415a (2d ed. 2003)). The recent decision in United States v. Apple, Inc., 952 F. Supp. 2d 638 (S.D.N.Y. 2013) demonstrates how this inquiry works.

The Apple case involved an alleged conspiracy between publishers of physical and electronic (e-) books, in conjunction with Apple, a retail distributor of e-books. Until Apple's entrance into the e-book retail market, the publishers had generally sold to retailers (most importantly, Amazon) under the "wholesale" model, in which the publisher set the "list" price for a book, while the retailer set the retail price. Id. at 649. Amazon had a practice of selling new and bestselling e-books for $9.99, regardless of the wholesale price. Id. The publishers disliked this strategy, because they feared that low-cost e-books would compete with and eat into sales of highly profitable hardcover books, and also threaten the viability of "brick-and-mortar" retail locations. Id. The publishers therefore used the entry of Apple's iPad and iBookstore to attempt to pressure Amazon into switching its pricing strategy and raising the price of its e-books.

The conspiracy between Apple and the publishers took the form of "agency" agreements that each publisher signed with Apple. Under this agency pricing model, the retailer (Apple)

(S.D.N.Y. 2012) (holding that series of vertical "agency" agreements between e-book publishers and distributor occurred "in a context that raises a suggestion of preceding agreement" among the publishers (internal quotation marks omitted) (quoting Twombly, 550 U.S. at 557)). An overall agreement inferred from reverse-payment settlements does not quite fit this mold, as reverse payment settlements are horizontal restraints (that is, an agreement between competitors at the same level of distribution, United States v. Topco Assocs., Inc., 405 U.S. 596, 608 (1972)), rather than vertical ones. Hence Plaintiffs seem to prefer the analogy to United States v. Masonite, 316 U.S. 265 (1945), in which the Supreme Court appeared to affirm a finding that a series of bilateral horizontal agency agreements between competitors in the hardboard industry also constituted an overall horizontal conspiracy.

would sell e-books at prices set by the publisher (within limits), and take a 30% commission for each sale. Id. at 661-62. This model resulted in less revenue per book for the publishers, because under the agency model, a book that retailed for $12.99 (a three dollar increase for the consumer) would result in only $9.10 revenue for the publisher (after subtracting the retailer's 30% commission). Id. at 665.

In addition to these terms, the agency agreements required each publisher to agree to adopt the agency pricing model with all its e-book retailers. Id. at 662. This promise to switch to the agency model was later replaced with a most-favored nation clause allowing Apple to sell e-books at whatever the lowest prevailing price was in the market. Id. This had the effect of forcing all of the publishers to stand firm in insisting that Amazon adopt the agency model, because if Amazon continued to sell e-books at $9.99, Apple would sell at that price as well. This would entail lower revenue for publishers, without the higher e-book prices the agency agreements sought to produce. Id. at 662-63. Apple "assured the [publishers] that they would all be getting the same terms, as would every other publisher who decided to sell e-books through the iBookstore." Id. at 664.

Although there was ample direct evidence of a conspiracy among the publishers, there was also evidence that the parallel agency agreements were contrary to the publishers' self-interest unless all of the publishers agreed to go along. As the District Court described it, "[t]he economics of the Agreements were, simply put, 'terrible' for the Publishers." Id. at 692. As a direct result of the agency model, the publisher was agreeing to make less money per e-book sold; "[s]ome of the Publisher Defendants predicted that the loss would be roughly 17% of their e-book gross revenue and amount to millions of dollars." Id. at 667. And any publisher that acted alone in raising prices for its e-books by switching to the agency model would face the double

whammy of significant lost sales to its competitors, as well as retaliation from Amazon. Id. at 692-93. Thus a conspiracy could be inferred because the economics of the agreements only made sense if all of the publishers had agreed to participate in the scheme.[12]

The Seventh Circuit made similar observations in Toys "R" Us. There, Toys "R" Us (TRU) sought a solution to its continuing lost sales to "warehouse" stores, which sold popular toys at prices that TRU could not match. Toys "R" Us, 221 F.3d at 931. To combat the problem, TRU entered into separate vertical agreements with major toy manufacturers, in which the manufacturers agreed to limit their sales of certain toys to the warehouse stores. Id. at 931-32. In reaching these agreements, TRU "was careful to meet individually" with each manufacturer. Id. at 932. Still, TRU told each manufacturer that it would be proposing similar terms to the others, and each manufacturer agreed to the terms "on the condition that their competitors would do the same." Id. TRU then enforced the agreements with each manufacturer, and "served as the central clearinghouse for complaints about breaches in the agreement." Id. at 933. The FTC found both that the individual vertical agreements violated the antitrust laws, and that the individual agreements concealed what was actually a horizontal agreement among the manufacturers to limit sales to the warehouse stores. Id.

As to the horizontal conspiracy, the Seventh Circuit affirmed, noting that an inference of conspiracy was supported by the fact that the agreement to limit sales to the warehouse stores was "an abrupt shift from the past"—the warehouse stores' share of toy sales had been growing prior to the agreements—and that the manufacturers would not normally be expected to "deprive [themselves] of a profitable sales outlet." Id. at 935. Because one manufacturer unilaterally limiting its sales to the warehouse stores would risk losing sales to its competitors, the

[12] The publishers had settled out of the case by the time the trial that produced the Apple decision was held. Apple, 952 F. Supp. 2d at 645.

agreements with TRU were found to be contrary to an individual manufacturers economic interest, unless the other manufacturers had agreed to accept the same deal.[13]

Here, the situation facing the Generic Defendants stands in stark contrast to those in Apple and Toys "R" Us. While the evidence in those cases indicated that the individual agreements were economically disadvantageous for the alleged conspirators, here, the settlement agreements with the Generics were economically beneficial. Moreover, there is no comparable evidence that the Generic Defendants were dependent on the universal agreement to make the settlements economically attractive. Indeed, the settlements seemed to offer the best of both worlds: an end to costly litigation, combined with lucrative business deals and an assurance that each Generic Defendant would not be disadvantaged regarding the entry of generic Provigil.

It is true that in United States v. Masonite Corp., 316 U.S. 265, 274 (1942), a case relied upon by Plaintiffs, the Supreme Court found it irrelevant that each "agent" in the conspiracy "acted independently of the others, negotiated only with Masonite, desired the agreement regardless of the action that might be taken by the others, [and] did not require as a condition of its acceptance that Masonite make such an agreement with any of the others." But Masonite is largely inapposite at this point in the inquiry, because it involved a conspiracy proven by direct evidence. See, e.g., id. at 270 (noting that in amending the agency agreements, a common "escrow agreement was signed by each of the companies and included the name of each of the other 'agents'"). It is obviously not a defense to price-fixing that the agreement was in the conspirators' economic self-interest. See United States v. Socony-Vacuum Oil Co., 310 U.S.

[13] As the Seventh Circuit pointed out, there was also direct evidence of a conspiracy among the manufacturers. TRU carried information between the manufacturers, assuring each that its agreement to limit sales to the warehouse stores would be met with similar acquiescence by its competitors. See Toys "R" Us, 221 F.3d at 932 ("TRU communicated the message 'I'll stop if they stop' from manufacturer to competing manufacturer.").

150, 218 (1940). Instead, the economic self-interest inquiry merely limits the inferences that may be drawn from ambiguous evidence. Matsushita, 475 U.S. at 588. Here, the fact that there is no evidence that the bilateral settlements contravened the Generic Defendants self-interest, and significant evidence that the settlements were in line with their economic self-interests, means that a fact-finder cannot not draw an inference of conspiracy.

Additionally, as noted previously, in evaluating circumstantial evidence of an overall conspiracy, a Defendant's motive to enter into the conspiracy must also be considered. In re Insurance Brokerage, 618 F.3d at 322. This factor also cuts against Plaintiffs' position.

A conspiratorial motive can arise where individual decisions are "interdependent," meaning that the optimal action for one party depends on the behavior of a competitor (and vice versa). Areeda & Hovenkamp, Antitrust Law ¶ 1411. Where benefits desired by the alleged co-conspirators can only be obtained through collective action, a motive to conspire may be present. See Elec. Books, 859 F. Supp. 2d at 684 (observing that conspiracy to change industry pricing structure presented a "classic collective action problem," in that the benefits "were shared across the publishing industry and not susceptible to capture by any single publisher"). On the other hand, motive will be lacking if the conspiracy is so unlikely to succeed that it "makes no practical sense." See Matsushita, 475 U.S. at 597 (granting summary judgment to defendants in predatory pricing conspiracy that would have required defendants to sustain losses for decades, with little hope of ever recouping them).

Here, there simply is no evidence of significant motive for the Generics to collude amongst themselves. Indeed, Plaintiffs have difficulty positing exactly what the Generic Defendants stood to gain from an overall conspiracy that they could not achieve through the one-on-one settlements with Cephalon. The Generic Defendants could only overcome Cephalon's RE

'516 patent for Provigil by obtaining a judgment that the patent was invalid, unenforceable, or not infringed or by being invited as a licensee to sell Provigil. Naturally, the parties could negotiate on when the license would begin, and could condition the license on the occurrence of certain events, such as entry by another generic version of Provigil. Importantly, none of this required agreement or participation by other Generic Defendants. On the contrary, the contingent launch provision would make the settling party indifferent to entry dates negotiated by any of the others. And with the presence of the contingent launch provisions, there was nothing to gain from conspiring with the other Generic Defendants to fix the April 6, 2012 entry date. Cephalon had little incentive to resist the contingent launch provisions because, as Plaintiffs observe, the real harm to the Provigil monopoly came from the first generic entry into the market. (See, e.g., Br. of the End-Payor Pls. 4 ("If just one of the Generic Defendants were to prevail and invalidate or void the patent, Cephalon's monopoly would be over.").) Beyond that, each additional generic entrant could cause only limited additional harm to Cephalon's bottom line. While this could have provided strong incentive for Cephalon to settle with all four Generic Defendants, it does not indicate that all four Generic Defendants had a motive to agree to do Cephalon's bidding.

The contingent launch provision, in addition to holding significant value for the Generic Defendants, was a contractual protection they could obtain entirely through independent negotiations with Cephalon. In fact, Teva (the first Generic Defendant to settle) might well have benefitted had another Generic Defendant continued the litigation and obtained a judgment that the RE '516 patent was invalid, since that would have allowed Teva to enter the market earlier, while still reaping substantial benefits from the agreement it made with Cephalon. As Apotex points out, Cephalon made approximately $132,000,000 in payments to Teva under the terms of the Cephalon-Teva settlement. (Apotex SOF ¶ 29.) The Generic Defendants had no reason to

conspire amongst themselves when they could obtain the best deal by agreeing to Cephalon's terms and hoping that the independent actions of the other Generic Defendants would produce a still better deal. This lack of motive is yet further reason why a jury could not conclude that Defendants' actions resulted from an overall conspiracy.

In taking the contrary view, Plaintiffs repeatedly conflate the existence of an agreement with its legality. The Direct Purchasers argue that "Defendants' perverse view of the law . . . would permit four competing companies who are contemplating entering a new territory held by the same long-term incumbent to agree to stay out of the market as long as their competitors did the same thing." (Opp. Br. of DPCP 19 n.20.) But this hypothetical assumes the proposition that Plaintiffs have the burden of proving: that an entry date/contingent launch agreement existed between all Generic Defendants and Cephalon. Without that proof, whether such an agreement would be illegal is simply irrelevant.

V. Conclusion

The record demonstrates that, over the course of several months in 2005 and 2006, Cephalon entered into four bilateral agreements to settle the then-pending patent infringement litigation against the Generic Defendants. These agreements contained identical entry dates and contingent launch provisions, and also had substantially similar structures. Plaintiffs posit that these features are explained by an overall agreement encompassing Cephalon and all of the Generic Defendants. There is, however, no direct evidence of such an agreement. Further, the circumstantial evidence does not support an inference of concerted, as opposed to independent, action. Accordingly, summary judgment must be granted to Defendants.

An appropriate order follows.